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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,847	12/08/2000	Liang C. Dong	ARC 2644 R1	2029

7590 07/03/2002

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EXAMINER	
WARE, TODD	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/733,847	Applicant(s) DONG ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Receipt of declaration filed 4-9-01, information disclosure statement field 6-6-01 and election filed 4-12-02 is acknowledged. Upon further consideration, the restriction requirement of 3-12-02 is withdrawn.

Claim Objections

1. Claims 18 and 36 are objected to because of the following informalities: interleukin appears to be mis-spelled as "interlenkin". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 39-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating viral infections, does not reasonably provide enablement for treatment of any condition in a subject responsive to antiviral medication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. These claims are directed to methods of treating a condition in a subject and are not enabled for the reasons set forth below with those reasons for the following "Written Description" rejection.

4. Claims 39-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors to determine whether a subject is responsive to antiviral medication and whether the unspecified condition to be treated would be affected by the antiviral agent would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that the instant antiviral compositions are administered to treat a viral infection and any condition (the conditions to be treated is unspecified) where an antiviral agent would be effective. However, the specification lacks a reasonable level of guidance for a composition/method for treating any condition where an antiviral agent would be effective, and working and/or prophetic examples are

absent. Applicant has not taught or defined what the conditions outside viral infections are.

(d, e & f) Although the art provides a certain level of guidance with regards to the use of antiviral agents to treat viral infections, these teachings do not provide sufficient guidance where the specification is lacking.

(g) The claims are broad because there is no guidance for the appropriate administration of a antiviral agents that would treat conditions other than viral infections as demonstrated in the art.

(h) The level of skill of those in the art is high.

The skilled practitioner would first turn to the instant specification for guidance in using the compositions for treating unspecified conditions other than viral infections, as claimed. However, the specification does not provide sufficient guidance for using the antiviral agents compositions, as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art demonstrates that administration of antiviral agents are effective for treating viral infections. Finally, said practitioner would turn to trial and error experimentation to make/use antiviral agents for treating conditions other than viral infections, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner. Thus, since the specification is not enabled for treating conditions other than viral infections, these claims do not comply with the written description requirement, since these methods require treatment of an **unspecified disease**. One skilled in the art would conclude that the inventors were not in possession of the claimed method of use.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "substantially" in the instant claimsis a relative term which renders the claim indefinite. The term "sustantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the terms "in-situ aggregation effect" and "improved bioavailability" are rendered indefinite

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4, 13-19, 27, 37, 39, 40-?asdf, 46-48, 50, are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004; hereafter '004).

'004 teaches microemulsion drug delivery systems for antiviral agents and other poorly soluble active agents. These formulations are then administered in capsules such as controlled release capsules and are liquids having the same ingredients as the instant claims (i.e. surfactant, oils).

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004; hereafter '004).in view of Alex et al (6,352,717; hereafter '717)

'004 is relied upon for all that it teaches as stated previously. '004 does not teach the specific protease inhibitor contemplated.

'717 is relied upon for teaching that saquinavir is a poorly soluble HIV protease inhibitor.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer saquinavir in the dosage form of '004 with the expectation that the formulations of '004 increase the bioavailability of poorly soluble active agents and the motivation to administer saquinavir which is poorly soluble.

12. Claims 5-12, 21-26, 28-37, 39-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004; hereafter '004) in view of Eckenhoff et al (4,692,326; hereafter '326) or Rudnic et al (5,952,004; hereafter '004) in view of Eckenhoff et al (4,800,056; hereafter '056) or Rudnic et al (5,952,004; hereafter '004) in view of Wong et al (5,324,280; hereafter '280).

'004 is relied upon for all that it teaches as stated previously. '004 does not teach the limitations set forth in claim 5. Briefly, the dosage form requires a walled compartment, an expandable layer, a capsule within the walled compartment, and an exit orifice.

'326, '056, and '280 all teach capsules having a compartment, an expandable layer, a capsule within the walled compartment, and an exit orifice. These capsules all comprise a hydrogel that swells when contacted with water to force the active agent from the dosage form. Controlled release of the active agent in the liquid ingredients is provided for a period up to days.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the liquid formulation of '004 with either '326, '056, or '280 with the motivation of providing a prolonged release formulation of the liquid active agent.

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004; hereafter '004).in view of Alex et al (6,352,717; hereafter '717)

'004 is relied upon for all that it teaches as stated previously. '004 does not teach the specific protease inhibitor contemplated.

'717 is relied upon for teaching that saquinavir is a poorly soluble HIV protease inhibitor.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer saquinavir in the dosage form of '004 with the expectation that the formulations of '004 increase the bioavailability of poorly soluble active agents and the motivation to administer saquinavir which is poorly soluble.

14. Claims 38 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004; hereafter '004) in combination with Eckenhoff et al (4,692,326; hereafter '326) and further in combination with Alex et al (6,352,717; hereafter '717) or Rudnic et al (5,952,004; hereafter '004) in combination with Eckenhoff et al (4,800,056; hereafter '056) and further in combination with Alex et al (6,352,717; hereafter '717)or Rudnic et al (5,952,004; hereafter '004) in combination with Wong et al (5,324,280; hereafter '280) and further in combination with Alex et al (6,352,717; hereafter '717).

'004, '326, '056, and '280 are relied upon for all that they teach as stated previously. None of these references teaches the specific protease inhibitor contemplated.

'717 is relied upon for teaching that saquinavir is a poorly soluble HIV protease inhibitor.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer saquinavir in the dosage form taught by either '026, '056, or '280

in the liquid formulation of '004 with the expectation that such a formulation increases the bioavailability of poorly soluble active agents and the motivation to administer saquinavir which is poorly soluble.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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June 29, 2002